K052122

MAR 2 9 2006

Section 5
510 (k) SUMMARY

Applicant:	Bisco, Inc. 1100 W. Irving Park Road Schaumburg IL, 60193
Contact Person:	Benjamin Lichtenwalner Tel: 847-534-6146 Fax: 847-534-6111
Date Prepared:	July 20, 2005

Trade Name:	**Bisco LED**
Common Name:	Dental Curing Light
Classification/Name:	Activator, Ultraviolet, For Polymerization **Class II per 21 CFR 872.6070**

Description of Applicant Device:

Bisco LED is a dual peak wavelength visible-light dental curing device, with built-in variable time settings allowing for a selection of time and wavelength.

Intended uses of Applicant Device:

Bisco LED, a visible-light dental curing device, is intended to provide the visible light required for polymerizing photo-initiated restorative materials used in dental practice.

Predicate Devices: TRANSCURE, MODEL 2910 (K022862) dated October 18, 2002.

Significant Performance Characteristics:

Bisco LED to TRANSCURE

Property	Bisco LED	TRANSCURE
Intended use	Dental Curing Light	Dental Curing Light
Physical Properties	One Battery Powered, Handheld Unit containing both blue and purple LED's	Two Battery Powered, Handheld Units with one for the blue and one for the purple LED's
Mechanical Properties	Uses LED's to selectively output either the blue or purple light.	Uses LED's to selectively output either the blue or purple light.

Side by side comparisons of **Bisco LED** to the predicate device **TRANSCURE** clearly demonstrates that the applicant device is substantially equivalent to the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2006

Mr. Benjamin Lichtenwalner
Regulatory Affairs Coordinator
Bisco, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K052122
Trade/Device Name: Bisco LED
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet activator for polymerization
Regulatory Class: II
Product Code: EBZ
Dated: March 20, 2006
Received: March 21, 2006

Dear Mr. Lichtenwalner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052122

510 (k) Number (if known): _____

Device Name: Bisco LED

Indications for Use:

Bisco LED is a LED dental curing light.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

[illegible] General Hosp.
[illegible] Dental Devices

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